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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

DHIMANT PATEL, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

EDWARDS LIFESCIENCES CORPORATION, BERNARD J. ZOVIGHIAN, LARRY L. WOOD, and SCOTT B. ULLEM

Defendants.

Case No. 8:24-cv-02221

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff Dhimant Patel ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Edwards Lifesciences Corporation ("Edwards" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Edwards' public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Edwards securities between February 6, 2024 to July 24, 2024, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Edwards' expected revenue for the fiscal year 2024, particularly as it related to the growth of the Company's core product, Transcatheter Aortic Valve Replacement ("TAVR"). Defendants' statements included, among other things, strong commitment to the TAVR platform, confidence in the Company's ability to capitalize on a subset of untreated patients through scaling of its various patient

activation activities, and continued claims of significant demand in allegedly lower-penetrated markets.

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Edwards' TAVR platform; notably, that the Company's claims and confidence relied far too heavily on their perceived ability to engage the claimed low-treatment-rate population of patients and an overestimation of the desire for hospitals and other care facilities to continue to utilize and otherwise commit resources to the TAVR procedures over newer, innovative treatment alternatives.

4. On July 24, 2024, Edwards unveiled below-expectation financial results for the second quarter of fiscal 2024 and, in particular, slashed its revenue guidance for the TAVR platform for the full fiscal year 2024. The Company attributed the TAVR setback on the "continued growth and expansion of structural heart therapies … [which] put pressure on hospital workflows." Investors understood this to mean that developments in new procedures, including Defendant's own Transcatheter Mitral and Tricuspid Therapies ("TMTT"), put significant strain on hospital structural heart teams such that they were under-utilizing TAVR, despite the Company's continued claim of a significantly under-treated patient population. Moreover, the Company announced three acquisitions during the second quarter designed to embolden their treatments alternative to TAVR, suggesting further that the company was aware of the potential for the TAVR platform's decelerated growth.

5. Investors and analysts reacted immediately to Edwards' revelations. The price of Edwards' common stock declined dramatically. From a closing market price of $86.95 per share on July 24, 2024, Edwards' stock price fell to $59.70 per share on July 25, 2024, a decline of about 31.34% in the span of just a single day.

JURISDICTION AND VENUE

6. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

7. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

9. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Edwards is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

11. Plaintiff purchased Edwards common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transaction(s) in Edwards is attached hereto.

12. Edwards Lifesciences Corporation is a California corporation with its principal executive offices located at 1 Edwards Way, Irvine, CA 92614. During the Class Period, the Company's common stock traded on the New York Stock Exchange (the "NYSE") under the symbol "EW."

13. Defendant Bernard J. Zovighian ("Zovighian") was, at all relevant times, the Chief Executive Officer and Director of Edwards.

14. Defendant Larry L. Wood ("Wood") was, at all relevant times, the Corporate Vice President and the Group President of TAVR and Surgical Structural Heart Therapies of Edwards.

15. Defendant Scott B. Ullem ("Ullem") was, at all relevant times, the Corporate Vice President and Chief Financial Officer of Edwards.

16. Defendants Zovighian, Wood, and Ullem are sometimes referred to herein as the "Individual Defendants." Edwards together with the Individual Defendants are referred to herein as the "Defendants."

17. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Edwards' reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information n available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

18. Edwards is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

19. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Edwards under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

A. Company Background

20. Edwards is an international company that researches, develops, provides products and technologies for heart valve repair and replacement therapies, as well as critical care monitoring solutions.

21. Edwards categorizes its therapies and technologies into four categories: Transcatheter Aortic Valve Replacement ("TAVR"), Transcatheter Mitral and Tricuspid Therapies ("TMTT"), Surgical Structural Heart therapies, and Critical Care therapies.

B. The Defendants Materially Misled Investors Concerning the Growth of Edwards' Flagship TAVR Therapies

February 6, 2024

22. On February 6, 2024, Edwards Lifesciences issued a press release publishing their fourth quarter results, highlighting, in pertinent part, that "Q4 TAVR sales grew 13 percent; constant currency sales grew 12 percent." Speaking on the results, CEO Bernard Zovighian was quoted stating, in relevant part:

> In 2023, our team made significant progress advancing transformational therapies for patients while delivering strong financial performance. Full year sales increased 12 percent, including impressive growth across each of our four product groups. We exited the year with strong momentum driven by our broad portfolio of innovative therapies. In 2024, we anticipate launching multiple breakthrough technologies globally and advancing important clinical trials as we embark on a new era of structural heart innovation. These breakthroughs, along with significant unmet patient needs, give us confidence in our ability to accelerate growth in 2025 and beyond.

23. The press release further detailed the Company's TAVR results, in pertinent part:

> For the quarter, the company reported global TAVR sales of $979 million, an increase of 13 percent versus the prior year, or 12 percent on a constant currency basis. Performance was driven by double-digit constant currency growth in the U.S., Europe and Japan. ***The company's competitive position was stable globally and local selling prices were also stable.***
>
> In the U.S., the company remains pleased with the continued expansion and adoption of the SAPIEN 3 Ultra RESILIA platform. This technology builds on Edwards' leadership in tissue technology and durability by combining advancements in tissue science with the industry leading SAPIEN 3 Ultra valve to offer the only dry storage transcatheter heart valve for U.S. patients today. ***The company remains confident that the future of TAVR remains strong driven by an increased focus on patient activation, a platform that delivers lifetime management for aortic stenosis patients, advances in new technologies such as RESILIA tissue, as well as indication expansion and increased global adoption.***
>
> Looking ahead, the company is pleased with the recently announced CE Mark approval for the SAPIEN 3 Ultra RESILIA platform and plans a disciplined launch in Europe. Long-term, the company continues to anticipate excellent opportunities for growth, as international adoption of TAVR therapy remains quite low.

(Emphasis added).

24. During the same-day Earnings Call, CEO Bernard Zovighian elaborated on TAVR's performance and confidently spoke about the Company's expectations for TAVR in 2024, stating, in relevant part,

> We are pleased with our strong 2023 financial performance with full year sales up 12% to $6 billion, including strong growth across each of our 4 product groups. We invested more than $1 billion in research and development, and we achieved key strategic milestones, including the introduction of new technologies and indication expansion to ensure sustainable healthy growth in the near, mid and long term. We exited the year with strong momentum with Q4 growth of 13% and TAVR

growth of 12%. These results were better than expected, driven by our broad portfolio of innovative therapies.

In 2024, we are well positioned to enter a new era of structural heart innovation. In TAVR, we are strengthening our leadership. We are experiencing strong adoption of our flagship SAPIEN 3 Ultra RESILIA and continuing enrollment in our ALLIANCE pivotal trial for our next-gen TAVR technology, SAPIEN X4.

…

Now I will provide some additional detail by product group. ***In TAVR, our full year 2023 global sales of $3.9 billion increased 10.6% year-over-year. Our U.S. and OUS sales growth rates were similar. In the fourth quarter, our global TAVR sales of 979 million increased 12% year-over-year. Performance was driven by double-digit growth in the U.S., Europe and Japan.***

The company's competitive position was stable globally and local selling price were also stable. In the U.S., we remain pleased with the continued expansion and adoption of a SAPIEN 3 Ultra RESILIA platform. This technology builds on Edwards' long-standing leadership in tissue technology and durability by combining advancements in tissue science with the industry-leading SAPIEN 3 Ultra valve.

Developing safe, effective and durable heart valve requires significant long-term commitment, and we are proud to be on 65 years on valve innovation while leveraging the expertise and know-how of more than 2,000 engineers and R&D specialists across the company. We are proud of uninterrupted leadership in structural heart and will continue to invest vigorously in these platforms. ***In addition, our scaling of patient activation initiatives, along with next-gen TAVR and additional evidence on asymptomatic and moderate AS patients position us for healthy, sustainable TAVR growth well into the future.***

Outside of the U.S., in the fourth quarter, our double-digit growth was comparable with our global TAVR growth, driven by Europe and Japan. Long term, we continue to anticipate excellent opportunities for growth. The international adoption of TAVR therapy remained quite low in many regions. In Europe, Edwards sales growth was driven by the broad-based adoption of our SAPIEN platform. ***It is***

> ***encouraging that the growth in Q4 was widespread across all major countries.***
>
> Looking ahead, we are pleased with the recently announced CE Mark approval for SAPIEN 3 Ultra RESILIA, and we are planning for a disciplined launch. We were pleased with our sales growth in Japan, and as expected, we grew faster than overall procedural growth. After more than 20 years of rigorous clinical experience and over 1 million patients treated with SAPIEN around the world, ***our TAVR platform is positioned for continued global leadership and strong sustainable growth.***
>
> ***Given the undertreatment rates, we are confident in the future of TAVR, driven by greater awareness, patient activation, a platform that delivers lifetime management for AS patients, advances in new technologies such as RESILIA as well as indication expansion and increased global adoption.***
>
> In TAVR, we will continue to drive global adoption of SAPIEN 3 Ultra RESILIA, present pivotal trial data from early TAVR, studying asymptomatic AS patients and enrolling ALLIANCE a pivotal trial studying the next-generation SAPIEN X4.

(Emphasis added).

25. During the question-and-answer segment of the earnings call, Defendants fielded multiple questions concerning TAVR and continued to display confidence in TAVR's market and growth potential in their answers during the following pertinent exchanges:

> <Q: Robert Justin Marcus – JPMorgan Chase & Co – Analyst> . . . Maybe one on the TAVR market. We have the exciting data from early TAVR coming later this year at TCT. How do you think about what that does to the TAVR market growth going forward? Do you put up double-digit growth in the fourth quarter, that's what guidance includes the next few years for the most part. How do you think about what's coming from low, intermediate and high risk and severe? And then how do you think about what asymptomatic adds? Is that just what helps keep you with double digit? Or can that help accelerate growth?

<A: Larry L. Wood> Yes. This is Larry. That's a great question. I think the first thing is we're just going to learn a lot from this trial. There's a lot of unknown questions out there in terms of what percentage of patients are truly asymptomatic when subjected to a stress test?

I think how fast do people progress and what happens to people why they're waiting. I think the biggest thing about it is, as we've talked about, and I spent a lot of time at the investor conference, the time from a patient to get diagnosed to treated is just really long. And a lot of that is the interpretation, the guidelines and this overlay of symptoms. And it's all really stand in the gears preventing the patients from moving through. And unfortunately, given the deadliness of the disease, a lot of people never actually make it to therapy.

I think with the early TAVR trial, assuming that it's successful, it will just streamline that process where we can just apply guideline criteria to aortic stenosis, and it won't require this additional evaluation of symptoms and people can just move through. ***But remember, only about 13% of patients right now with severe aortic stenosis actually get treated. So there's a huge undertreatment right now. We think asymptomatic just adds to that.***

<A: Bernard J. Zovighian> In addition, Robbie, what I like is our commitment to -- after 20 years of TAVR, we are still in a super committed to bring big evidence. Look at these 2 trials, progress and early TAVR. This is a potential for sure not to learn more, but also to expand indication. To change the guidelines. So as a leader in the space, for sure, we like it, we are committed. ***But I believe that in the next 10 years, here in TAVR, we are going to see some very exciting things happening.***

. . .

<Q: Patrick Andrew Robert Wood - Morgan Stanley – Former Research Analyst> Amazing. I guess maybe for the first one on TAVR and Japan in general. Do you think you've been taking back some share post trialing. It sounded like you feel very good about the market, and you were taking back some share on that side. Just any color you could give there would be great.

<A: Larry L. Wood> Sure. I think what happens when new technology comes into Japan just because of the way the certification process works and people having to move through that process, that certainly had an impact for us. ***I think in Q4, we grew faster than the market***. And I think that really relates to some of the trialing ending and people kind of moving back to our platform. But this is sort of something that goes on, ***but we're very pleased with how we grew in Japan in Q4 and continue to look forward to that market growing because it's a very -- it's a much lower penetrated market than places like the U.S. and Europe. So we continue to see that as a long-term growth driver for us.***

. . .

<Q: Vijay Muniyappa Kumar – Evercore ISI Institutional Equities – Senior MD and Head of Medical Supplies & Devices and Life Science Tools & Diagnostics Team> Congratulations on a nice sprint here. Maybe one last question on EVOQUE . . . Like, tehre's a reason this valve was a forgotten valve. So I'm curious what wakes up physicians to take the valve seriously, maybe compare in contrast on how this adoption curve could look like versus I don't know if TAVR is a good example, but I would love your comments.

. . .

<A: Bernard J. Zovighian> . . . And we are very excited. Think about TAVR. 20 years later, we are still generating evidence. We are still innovating with Ultra RESILIA X4. ***We still believe that there is a way for TAVR to grow healthy double digit in the many years to come globally.***

. . .

<Q: Matthew Stephan Miksic – Barclays Bank PLC – Research Analyst> Okay. And then the TAVR side, did you see any results you feel from these field activations and patient activation efforts in Q4? Or is that something that's still to come?

<A: Scott B. Ullem> Matt, I think we saw some benefit from the patient activation initiatives that we have in place. It's tough to isolate those from the other efforts that we have underway to continue to support the

> growth of TAVR. ***But no, that's certainly helping drive growth in the fourth quarter and beyond.***
>
> <A: Larry L. Wood> ***Just to add on to this, I mean, I think it'd be incorrect to say our patient activation efforts are just starting to pay dividends now***. We've been doing patient activation for the last, I don't know, 5 or 6 years through our digital campaigns, through some of our website stuff, some of our patient resources, some of the general cardiology awareness events we do and a number of other things that have been driving this. ***So I think patient activation has been contributing all the way along the way.***
>
> ***I think what we're talking about now, though, is a much more sophisticated approach and program to really tapping in to these untreated patients that are in the system, but hospitals don't really realize that they're there. And how do we bridge those gaps. And that's really where our activation now is because we know the patients are there. We know they're diagnosed with an echo, but they're not moving. And so it's just a matter of tapping into those patients in the right way and getting the accelerated through the system.***
>
> <A: Bernard J. Zovighian> What's fair to say though is, in the past few years, we have done many pilots, many initiatives. We have extracted so many learnings. ***What we are doing right now is scaling. We are scaling and spending. We are spending resources in Q4 last year, this year and the next few years. So you are going to see more and more because we believe there are so many patients in need not receiving a treatment.***

(Emphasis added).

April 25, 2024

26. On April 25, 2024, Defendants published their first quarter fiscal year 2024 results, announcing that "Q1 TAVR sales grew 6%; constant currency sales grew 8% adjusted for billing days."

27. During the corresponding earnings call discussing the results, Defendants provided some clarity to TAVR's slow growth in the first quarter. In pertinent part, CEO Zovighian stated,

Now I will provide some additional detail on Q1 results by product group. In TAVR, first quarter global sales of $1 billion increased 8% year-over-year when adjusted for billing days. Q1 marked the first quarter that Edwards TAVR sales exceeded $1 billion, an exciting milestone for our team and a testament to clinician confidence in our leading technology. Performance was driven by growth in the U.S. and Japan, Edwards' global competitive position and selling prices were both stable. In the U.S., our year-over-year first quarter TAVR sales growth rate was higher than our global constant currency growth rate. We estimate total procedure growth was stable. Procedure volumes increased as the quarter progressed.

We remain pleased with the continued performance of our best-in-class TAVR platform. SAPIEN 3 Ultra RESILIA, which build on Edwards' long-standing leadership in tissue technology and durability. This innovative technology now makes up the majority of our sales in the U.S. This platform is supported by the robust real-world data for more than 10,000 patients in the TVT Registry that demonstrated excellent outcomes across hundreds of centers.

. . .

Outside of the U.S., in the first quarter, our constant currency TAVR sales growth was slightly below our global TAVR growth. Strong growth in Japan and the rest of the world was partially offset by slower-than-expected growth in Europe. In Europe, our results were softer than expected in Q1. But we expect full year 2024 performance to normalize. We are actively preparing for the launch of SAPIEN 3 Ultra RESILIA in Europe, and we anticipate introducing the technology into the European market in Q2.

In Japan, we continue to see strong TAVR adoption driven by SAPIEN 3 Ultra RESILIA. We believe AS remains a significantly undertreated disease among the substantial elderly population and continue to focus on expanding the ability of an evidence supporting this therapy.

In closing, we are confident that Edwards is positioned for healthy and sustainable TAVR growth well into the future, driven by our development of differentiated TAVR technology, our deep commitment to advancing patient care through high-quality clinical evidence and our investment in patient activation initiatives.

> Importantly, we are proud of our groundbreaking research into the treatment of AS through our early TAVR and PROGRESS trial, which could fundamentally change how AS patients are treated. We remain confident in our full year TAVR sales growth of 8% to 10%. We expect higher year-over-year second half growth rate than in the first and second quarter.

(Emphasis added).

28. The question-and-answer portion of the call followed, which again heavily featured questions related to TAVR's growth and ongoing potential. In their responses, Defendants again touted TAVR's success and displayed confidence in continued growth for the product portfolio in relevant part during the following exchanges:

> <Q: Robert Justin Marcus - JPMorgan Chase & Co. – Analyst> Great. Maybe a follow-up. I caught the comments that the U.S. TAVR grew faster than the global organic TAVR growth rate and that procedure as accelerated throughout the quarter. So how are you thinking about TAVR growth for the rest of the year? And do you feel like the U.S. has finally recovered after some of the setbacks you saw during the disruptive years of COVID?
>
> <A: Bernard J. Zovighian> Thanks, Robbie. Let me start, and again, I will ask Larry to add some insights here. ***So when we put together a guidance for the year, the guidance 8% to 10%, we knew that the growth will ramp throughout the year and that Q1 will be our lowest growth quarter. So we feel we are confident about our 8% to 10%. We feel confident about what's happening in the U.S. Share and price are stable. So we feel good about all of that.***
>
> Larry, you want to add anything?
>
> <A: Larry L. Wood> Yes. I don't have a lot to add. We saw good progression throughout the quarter. It's always a little slow in January as we come out of the break, but we are pleased with how the quarter went overall. And we remain excited about the year. We have a lot of activities on patient activation. We have a huge data set coming out of TCT that I think all of us are going to be excited to see what that say,

what those data say and how they inform the field. ***And so I continue to believe we have a long runway long term with TAVR and it is good to see the U.S. kind of out COVID, I think, finally in the rearview mirror, and we can just focus on accelerating patient care.***

. . .

<Q: Travis Lee Steed – BofA Securities – Managing Director> Congrats on a good quarter. Maybe on TAVR again, curious why European growth was slower than expected. And then on the billing days, were those U.S. or OUS and those come back in any quarter?

<A: Larry L. Wood> Yes, thanks. ***Yes, overall, we felt good about the quarter, and we just talked about the U.S. We saw a lot of strength in Japan, but Europe was -- it grew year-over-year and it grew sequentially***, and we lost a couple of billing days. But even with that, ***we were a little bit disappointed with our overall growth in Europe.*** We saw some pretty aggressive pricing from competitors that I think led to some trialing. But we're really excited that we're launching S3UR that actually starts this month, and we're excited to bring that technology to Europe, ***and we expect these to normalize through the course of the year.***

. . .

<Q: Travis Lee Steed> All right. That's helpful. And then on TAVR and some of that you've been doing with Egnite and kind of helping drive center growth and diagnosis. Curious to see how that's going and at what point do you start to kind of scale those programs out and an impact on -- see the impact on TAVR growth?

<A: Larry L. Wood> Yes. ***We have a lot of patient activation activities where there's a lot of work that we do.*** We have multiple fronts, and Egnite is just one part of our strategy there. But we're excited about what these technologies can do. ***And there are so many patients, if you look at the [indiscernible] publication, and I know he's spoken to you guys before, there's just a lot of patients upstream that aren't moving through the system at the speed in which they should***. And I think there's a patient identification aspect, there's a referral aspect.

So we have multiple work streams working on this. But I think the appreciation and understanding for the undertreatment of aortic stenosis is growing. And I think as that grows and people start to understand the magnitude of the problem, I think it gives more opportunity for our patient activation strategy to take hold.

<A: Bernard J. Zovighian> And maybe in addition, Larry, I'm very proud about what we are doing. We are the only one basically having a deep commitment to advancing science for AS patients through the progress and early TAVR trial. ***So this is truly our commitment, but we feel that there is a ton of potential. These patients are underdiagnosed [indiscernible], and we are committed to offer treatment for these patients. So as a company, very proud about how we do all of this.***

. . .

<Q: Lawrence H. Biegelsen - Wells Fargo Securities, LLC – Senior Medical Device Equity Research Analyst> I just wanted on TAVR, I wanted to confirm, Bernard, that Q2 TAVR growth will be better than Q1, in response to Robbie's question. And why do you expect TAVR growth to accelerate in the second half? And how are you guys factoring in the SMART trial results? And I have one follow-up.

<A: Larry L. Wood> Yes. Yes, we do expect to have procedures to ramp. That's always been a part of our plan, and so we continue to expect that to happen. And I think it's a lot of things, Larry, I think it's a lot of our patient activation work. But it's also just the market continues to improve, and ***we're very pleased where we finished Q4 last year. We were happy with the ramp in Q1. So I think we do expect to see an increase in Q2 over Q1. But even with that, we expect the second half to have a higher growth rate than the first half. So I think that that's good.***

. . .

<Q: Matthew Stephan Miksic – Barclays Bank PLC – Research Analyst> Just one question on sort of TAVR and transcatheter valve growth, and I'll just keep it to one. If you could maybe talk a little bit about the launch of EVOQUE and the activity that, that drives in some of your major centers. And I guess how you're -- you and the team in

> the field is kind of managing those activity levels [indiscernible] centers versus the continuing volumes that they perform in TAVR. Just maybe any color or thoughts on how that might play into the total transcatheter business?
>
> . . .
>
> <A: Bernard J. Zovighian> ***It is fair to say that so far, we have not faced a big challenge in terms of center, having a lack of capacity to be able to treat the patients, whether TAVR patients or EVOQUE patients***.
>
> . . .
>
> <Q: Shagun Singh Chadha – RBC Capital Markets – Research Analyst> Sorry about earlier. It just sounds like U.S. TAVR growth was high single digits. Is that fair? Was it about 10%? And other drivers that can get you to consistent double-digit growth in the foreseeable future? Just what's your confidence there?
>
> . . .
>
> <A: Scott B. Ullem> Yes. I'll take the first part of that about U.S. TAVR growth. We try not to be too specific about breaking down every region. But what we can say is that TAVR in the U.S. grew faster than our global underlying growth rate for TAVR in the first quarter. Larry, do you want to talk about the other pieces?

(Emphasis added).

29. In closing, CEO Zovighian pertinently noted on the call that "TAVR, for sure, it is the largest business for us. It's still our #1 focus. TAVR has a lot of growth potential."

June 5, 2024

30. On June 5, 2024, Defendant Ullem presented on behalf of the Company at Jefferies 2024 Global Healthcare Conference. During the interview-structured presentation, CFO Ullem pertinently discussed TAVR's impact on Edwards' guidance and outlook for FY 2024 and beyond. In relevant part:

<Q: Matthew Charles Taylor, Jefferies LLC, Senior Analyst> So let's start with TAVR. Could you talk a little bit about the TAVR trends in Q1? I guess you grew a little over 6%, about 7%. And talked about some trialing in Europe and some pricing pressure there.

So I guess, could you give us an overview on what's happening, if there's any update in Q2? And then overall, how do you expect the TAVR market to grow and your growth to be within that?

<A: CFO Scott B. Ullem> Yes. So yes, ***TAVR, we started out in the first quarter with lower year-over-year growth rate than we expect for the full year***. Our guidance for TAVR for the year is 8% to 10%. ***We always knew that the first half of the year was going to be a lower year-over-year growth environment than the second half of the year. That's been our plan, and we saw that in the first quarter again.***

Just breaking it down between the 4 areas of the world where we focus our attention, U.S. grew faster than the OUS business in the first quarter. Japan was our fastest big growing region in the first quarter. In Japan, we saw some competitive pressure last year that abated in the second half of last year, and we're back to more of a normalized growth curve in Japan. ***In Europe, we were surprised a little bit in the first quarter by some of the competitive trialing that we saw. We expect the European environment though to normalize as we get later into 2024.***

And then the Rest of World where, today, we're in TAVR in over 60 countries. And so there are big growth opportunities in other areas of the world, and that's been a pretty exciting area for us in 2024, and we think it will be in '25 and beyond.

Overall, the business is performing well. There's still an environment now where around 13% of patients who have aortic stenosis, severe aortic stenosis get treated today. And it's a remarkably low treatment rate, especially relative to other diseases with a high mortality rate like severe aortic stenosis, and it ***gives us confidence that we should keep investing in this opportunity.***

In fact, we just finished enrollment in an important clinical trial studying aortic stenosis in patients who just have a moderate form of the disease, where it has not progressed yet to severe. And we think there's a real opportunity to help patients who need earlier intervention

> to get their valve replaced and today are not on indication to do so with TAVR.
>
> There's another trial that's actually reading out later this year at the TCT Conference, studying patients who have severe aortic stenosis without symptoms. And if the trial shows what we think it will, it will be an important opportunity to make this therapy available to patients who have this deadly disease, but who did not get screened for care because they don't have symptoms today.
>
> So those are some of the factors that are underlying our current performance and what we think are going to benefit our longer-term growth trends as well.

(Emphasis added).

31. The above statements in Paragraphs 22 to 30 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information pertaining to the Company's projected revenue outlook and anticipated growth while also minimizing risk from seasonality and macroeconomic fluctuations. In truth, TAVR's growth was at risk of decelerating. Edwards' optimistic reports of TAVR's growth and anticipated ramp in the second quarter and further ramp throughout the fiscal year fell short of reality as Defendants "patient activation activities" failed to reach the perceived low-treatment-rate population TAVR's growth relied upon obtaining and, further, Defendants relied far too heavily or otherwise overstated hospital desire to continue to utilize the Company's TAVR procedures over newer, innovative structural heart therapies.

C. The Truth Emerges during Edwards' Second Quarter Earnings Report

July 24, 2024

32. On July 24, 2024, Defendants released their Q2FY24 TAVR results below expectations and lowered FY24 projections for TAVR in pertinent part as follows:

Highlights and Outlook

- Q2 sales grew 7%; constant currency sales grew 8%
- ***Q2 TAVR sales grew 5%; constant currency sales grew 6%***
- Q2 TMTT sales grew 75%; increasing contribution to Edwards' growth
- Q2 EPS of $0.61; adjusted1 EPS of $0.70
- Significant TAVR and TMTT clinical evidence to be presented at TCT in October 2024
- Positive EVOQUE introduction with excellent patient outcomes; NCD process on track
- Critical Care sale expected to close late Q3 2024
- Expect full-year 2024 Edwards sales growth of 8 to 10%; ***lowering TAVR guidance to 5 to 7% from 8 to 10%***; increasing TMTT guidance to the higher end of $320 to $340 million

"Second quarter total company sales growth of 8 percent reflected strong contributions from our rapidly growing TMTT product group, ***offset by lower-than-expected growth in TAVR***," said Bernard Zovighian, CEO.

. . .

Transcatheter Aortic Valve Replacement (TAVR)

In the second quarter, ***the company reported TAVR sales of $1.0 billion, which grew 5%, or 6% on a constant currency basis***. Edwards' competitive position did not meaningfully change globally, ***although the company experienced some regional pressures***, and pricing was maintained.

Edwards remains pleased with the performance of its SAPIEN 3 Ultra RESILIA platform, which is the leading platform in the U.S. and Japan. In the second quarter, Edwards began the introduction of the SAPIEN 3 Ultra RESILIA valve in Europe. The RESILIA tissue's anti-calcification technology is designed to address one of the primary causes of reintervention following heart valve replacement and provides the potential to extend the durability of the valve.

(Emphasis added).

33. During the same-day earnings call, CEO Zovighian elaborated on the setbacks, highlighting that TAVR grew significantly more slowly than anticipated and restated less than one month before the second quarter's close. In pertinent part, Defendant Zovighian stated:

> ***In the U.S., our year-over-year second quarter TAVR sales growth was slightly below our global constant currency growth rate***. We believe our U.S. competitive position was largely unchanged. ***Second quarter U.S. TAVR sales grew slower than expected.*** The continued growth and expansion of structural heart therapies, including newly approved tricuspid therapies and other fast-growing structural heart therapies put pressure on hospital workflows, which impacted TAVR. These pressures were also observed in the recent spike in emergent TAVR cases as reflected in claims data as centers adopt these new therapies, and they become part of their standard processes, we expect this will stabilize.
>
> . . .
>
> In closing, ***we now anticipate second half TAVR sales growth similar to the first half year-over-year growth rate, 5% to 7% full year growth rate versus previously guidance of 8% to 10%.*** This equates to full year global TAVR sales of $4 billion to $4.2 billion.

(Emphasis added).

34. During the call, Defendants also highlighted Edwards' recent acquisitions, stating in pertinent part:

> Earlier this month, we announced the acquisition of Innovalve. Innovalve early-stage technology will add to a growing pipeline of innovative therapy in TMTT, and we expect to close the acquisition later this year. We further expect that Innovalve technology, combined with Edwards expertise in mitral disease will enhance the company TMVR technologies to address large unmet structural heart patient needs and support sustainable long-term growth.
>
> . . .

> Turning down to the strategic acquisition of JenaValve and Endotronix. These acquisitions provide an expanded opportunity in new therapeutic areas to address the unmet needs of AR and heart failure patients around the world. Furthermore, the acquisition reflects our deep commitment to advancing patient care through our unique strategy and reinforce our confidence in Edwards sustainable long-term growth. Starting with JenaValve, a pioneer in the transcatheter treatment of AR, a deadly disease that impacts more than 100,000 patients in the U.S. alone and is largely untreated today. Edwards anticipate U.S. FDA approval of JenaValve Trilogy Heart Valve System in late 2025, which will represent the first approved therapy for patients suffering from AR. Edwards will invest to accelerate development of this novel technology to enable earlier patient access. As the pioneers in valve innovation, we believe we are best positioned to lead this next frontier of aortic valve disease treatment. We expect this to be the beginning of a long-term iterative strategy similar to TAVR.
>
> Turning to Endotronix. Edwards made its first investment in the company in 2016. So we are very familiar with the technology, the opportunity and the employees, many structural heart patients Edwards serve today also suffer from heart failure with a limited options. This acquisition will expand Edwards Structural Heart portfolio into a new therapeutic area to address the large unmet needs of patients suffering from heart failure, which we believe has a significant long-term growth opportunity.
>
> Last month, Endotronix received FDA approval for Cordella, an implantable pulmonary artery pressure sensor that directly measure the leading indicator of congestion, following the publication of the successful U.S. pivotal trial. We are pleased to enter the structural heart therapeutic area with innovation, world-class science and clinical evidence to provide access to life-saving technologies for patients around the world. We anticipate this investment will strengthen its leadership in structural heart innovation and represent long-term growth opportunities. Minimal revenue contribution from JenaValve and Endotronix is expected to begin late in 2025.

35. In the question-and-answer segment, Defendants elaborated on the TAVR setback, driving home that TAVR's growth was slower than anticipated, and

not because of a lack of patients. In pertinent part, the following exchange transpired:

> <Q: Robert Justin Marcus, JP Morgan Chase Analyst> Two for me. Maybe first, you talked about it in the script, but I was hoping you could give a little more. TAVR has clearly come in below your initial expectations for the year. The guidance has moved down, the U.S. is slowing, OUS is facing pressure. We saw two of your smaller competitors, but still competitors see pretty nice growth sequentially and year-over-year so their TAVR is taking more in Europe and outside the U.S., Japan. How are you thinking just about the underlying growth rate of the TAVR market? And I appreciate it's a huge opportunity, and it's still a lot to conquer in the future. But in, let's call it, the short to medium term, how are you thinking about the overall market growth? And is there anything you can do to help accelerate it?
>
> <A: Larry L. Wood> Thanks, Robbie. Well, obviously, ***we expected growth rate to be higher in Q2 than it was***. We had a slow start in Q1, but we were exiting March, and we felt good about where we were. So ***this did come as a surprise***. ***I think when we reflect back on it and we look more deeply at it, you have to think about all the things that have shown up that are going to the same structural heart team at all of these hospitals.*** We're seeing rapid growth in mitral repair. ***We're seeing a lot of growth in other procedures. And we had 2 new therapy approvals recently in the tricuspid space.***
>
> I think a little bit we looked at the procedure volumes and the hospitals have shown a pretty good job of being able to handle these things. ***We probably underestimated the burden of even starting these new programs, even preparing to start these new programs because you have to screen the patients early on, there's a lot of learning, screen failures, all of those things. And I think it's just taxing the teams***.
>
> Now in terms of things we can do to help, ***there are certainly things we can do to help. We can do a lot of imaging workups and take some of the load off the team. We can do device prep. We can come in with our benchmark program and teach them efficiencies and do those things***. But once the program has been optimized, that it really does come down to the hospital to add another team or add additional days and do those sorts of things. So there are some things we can do, but we can't do everything.

I think the other thing is, ***I think, highlighting this for the clinicians. And we're very confident. This isn't some slowdown because there's a lack of patients***. We didn't see any of the fundamentals change in terms of new data that was concerning or any of these things. ***I think it's just a matter of the workflow right now. And we need to be able to engage with hospitals, but two important things we saw is we saw an increase in time from CT to procedure, which indicates patients are waiting longer.***

And the other thing that we saw was a sharp increase in the number of cases being coded as emergent versus routine. And I think that speaks to these patients waiting in the queue as these workflow issues sort out. So I think hospitals will certainly do that in time. These patients don't wait well, and we know that there's a lot of them, but we're going to have to continue to work through that with the hospitals.

<A: Bernard J. Zovighian> So let me add on what Larry said. ***To be fair, we are contributing a little bit on this pressure. At the same time, we are benefiting. If you look at the TMTT growth in the quarter, so we are contributing and benefiting at the same time.***

Now a big picture. We have seen this picture in the past, don't you think we have similar hospital facing like more to do, more technology to adopt, to be trained on new technologies and they are very good at scaling, they are very good at learning, they are very good at adapting, they are in their workflows in the cath lab. So we believe it is temporary. And we are -- Daveen also with this team are with Larry partnering on this one. So we are fully focusing on this one, helping in the hospital. But we have faith, the hospital are going to do that, like they did it in the last 10 years.

<Q: Robert Justin Marcus> Great. And maybe a follow-up to that. Guidance implies roughly stable TAVR first half into second half. I appreciate the need to be conservative, but it sounds like some of the learnings you saw in second quarter could possibly help in the back half of the year. Maybe just walk through the thought process of the 5% to 7% TAVR guide and kind of what you're baking into that?

<A: Scott B. Ullem> Yes. We're -- I mean, it's pretty straightforward, which is we're baking into it, similar market conditions the year-over-

year calculation is pretty similar. ***Fourth quarter comp gets a little bit tougher, but we think that all things considered that 5% on the low end, 7% on the high end, captures the likely scenario for the second half combined with the first half that we've already reported.***

<A: Bernard J. Zovighian> We believe, to add in on that, what we believe early TAVR at TCT. It will be already almost the end of a quarter, Robbie, so TCT in late October. So we believe it will have a very minimal impact in Q4. So it is why we didn't want to take too much risk here.

. . .

<Q: Travis Lee Steed – BofA Securities – Managing Director> I wanted to go back and circle back on Robbie's question on TAVR. It feels like there's a little bit more of a change here. Just 3 months ago, you thought TAVR was going to accelerate over the course of the year. I thought the 8% to 10% at the beginning of the year was supposed to be a conservative guide. So I just want to understand like -- I hear what you're saying on TMTT, but that's a small number of fractions versus the overall TAVR centers. So I don't know if there's anything else that you'd kind of call out or kind of what surprised you on the TAVR line. I know there was some of the European stuff and competition there that you called out last quarter. Just understanding kind of the full change and why you got the initial TAVR guide wrong at the start of this year?

<A: Larry L. Wood> Yes. Thanks, Travis. Yes, when we exited Q1, we felt we were on a good ramp and we thought we were on a good pace, and that's why we reiterated guidance and we felt good about it. And ***we just didn't see that play out in Q2 the way that we anticipated***. And by no means do I mean to say this is all Daveen's fault and it's all EVOQUE because that's not accurate or fair when you look at the number of procedures.

I think it's the cumulative impact of all the things that have hit the structural heart teams over the last year. And it's one of those things. You can always increase a little capacity, work a little harder, increase a little capacity, work a little bit harder. But then at some point, you reach a breakpoint when it's simply too much. And the heaviest lift for centers is starting a program. And it's not just the procedure volume. It's all that screening and all of the case reviews and all the interaction

that just consumes a lot of resources and a lot of time. And the training, you don't have to go to training and observed cases in many cases and all of those sorts of things. ***And so I think it's just the cumulative impact of those things that happen over time.*** And we did see the slowdown more acutely in large centers and small centers, which fits a little bit of the model as well in terms of the centers that are most likely to be looking to start these new programs and are competitive about that.

And again, I said it earlier, but we did see a spike in emergent cases over routine cases. And I think that fits what we're saying as well. But that's not going to be sustainable for people. Emergent cases have more complications. They don't have as good of patient outcomes and people will have longer length of stay, and that's going to adversely impact patients and the hospitals themselves. ***So I think people will have to adjust it over time. And we're going to have to work closely with them to help them do that.***

. . .

<Q: Matthew Charles Taylor – Jefferies LLC – Senior Analyst> I guess I wanted to follow up on some of your U.S. TAVR commentary and the workflow angle because I'd like to understand better why you think it's showing up so acutely now, I guess, given you're still in a limited rollout of EVOQUE, is this an issue that's been matriculating for a while, and we're just seeing it more now? And could you help us understand your history there, you talked about the impact on coronary. How long do you think it will take for the hospital to adjust? Is this a 1 quarter or 3-quarter issue? Does it take years? What kind of time frame would you put on them adjusting to accommodate the additional workflows?

<A: Larry L. Wood> Yes. Thanks, Matt. The thing that I would say is, I guess, if I were to draw an analogy, if you had a factory and you saw demand for your product going up, you can always add a little more hours and you always have a little bit of excess capacity and you can adjust to those things. ***I think there is just a point in time where you hit a wall and it's harder to do those things. And I think that's a little bit of what we saw here. It's the cumulative effect of all of these things that have played out over time.***

> If you look at total cath lab procedures for the structural heart team in the last 3 years, it's probably close to double during that period of time, which is a lot of growth that these teams are having to absorb and they're having to adapt to. And I think it will take time. ***And again, when you're starting these new programs on these new therapies, that's the heaviest lift part of it. And again, I think this gets corrected over time, and we'll work closely with the hospitals to do that. But we reflected that in our guidance and just wanted to be realistic and not be toned after what's happened***. But the same thing I'll tell you is ***none of us are happy with the growth rates. None of us are happy adjusting guidance, and we're going to be working as hard as we can to do everything we can to restore the growth to where we think it should be.***
>
> <A: Bernard J. Zovighian> ***And we are not happy as a company. The patients are not happy, the physicians are not happy, the hospitals are not happy***. So we are all fully aligned about it is a problem, we need to solve it. So it is why also we are confident here.

(Emphasis added).

36. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the February 6, April 25, June 5, 2024 earnings and shareholder calls. On those calls, Defendants continually praised their TAVR products' alleged growth, foreseeing a growth ramp in the second quarter which would continue to grow into the back half of the year due to their confidence in accelerating patient care through activation activities designed to reach a claimed subset of untreated patients. All-the-while Defendants simultaneously touted their commitment to TAVR as their key flagship product and continually minimized the risks associated with competition and the potential impact of the macroeconomic hospital environment on TAVR's sales numbers.

37. Investors and analysts reacted immediately to Edwards' revelation. The price of Edwards' common stock declined dramatically. From a closing market price

of $86.95 per share on July 25, 2024, Edwards' stock price fell to $59.70 per share on July 26, 2024, a decline of about 31.34% in the span of just a single day.

38. A number of well-known analysts who had been following Edwards lowered their price targets in response to Edwards' disclosures. For example, Deutsche Bank, while dropping their price target, questioned the Defendants' explanation for the TAVR setbacks, stating, in pertinent part:

> Management talked about physician capacity as the issue versus demand, but we struggle with that explanation. Because aortic stenosis has a higher mortality than either mitral or tricuspid regurgitation, ***management looks to be implying that doctors could be prioritizing lower mortality patients over higher mortality ones – which we struggle to understand***.

(Emphasis added).

39. The analyst went on to posit an alternate theory: that TAVR was not in as high demand as the Company claimed:

> EW announced three acquisitions in the past few weeks: (1) JenaValve; (2) Endotronix; (3) Innovalve. ***When a growth company announces a series of acquisitions as its key product begins to slow, it increases the doubt if the TAVR market is as strong as management had previously discussed***. When done in conjunction with this earnings release, it will likely add fuel to the bear fire.

(Emphasis added).

40. Similarly, Canaccord Genuity, while also cutting their price target, noted that "[t]he miss in Edwards' core business certainly concerned investors, evident by the stock price movement after the close and the volume of TAVR questions during the conference call."

41. Additionally, J.P. Morgan, while dropping their "Overweight" rating down to "Neutral" and implementing a sizeable slash to their price target, highlighted that the revelation of "TAVR growth decelerating" forced them to cut

predicted growth for the Company in 2025 and 2026, as they "don't expect a quick rebound" for Edwards.

42. The fact that these analysts, and others, discussed Edwards' shortfall and below-expectation projections suggests the public placed significant weight on Edwards' prior revenue and sales estimates. The frequent, in-depth discussion of Edwards' guidance confirms that Defendants' statements during the Class Period were material.

D. Loss Causation and Economic Loss

43. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Edwards' common stock and operated as a fraud or deceit on Class Period purchasers of Edwards' common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Edwards' common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Edwards' common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

44. Edwards' stock price fell in response to the corrective event on July 24, 2024, as alleged *supra*. On July 24, 2024, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Edwards' forecasting processes and growth guidance.

45. In particular, on July 24, 2024, Edwards announced TAVR's growth was decelerating, as the results for the second quarter of fiscal year 2024 were below expectations and the Company further reduced their own prior guidance for TAVR by 3%. This setback and reduction, coupled with Defendants' explanations for the result and the announcement of multiple acquisitions, suggests the demand for TAVR was not as strong as Defendants previously claimed.

E. Presumption of Reliance; Fraud-On-The-Market

46. At all relevant times, the market for Edwards' common stock was an efficient market for the following reasons, among others:

(a) Edwards' common stock met the requirements for listing and was listed and actively traded on the NYSE during the Class Period, a highly efficient and automated market;

(b) Edwards communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(c) Edwards was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Edwards was reflected in and incorporated into the Company's stock price during the Class Period.

47. As a result of the foregoing, the market for Edwards' common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in Edwards' stock price. Under these circumstances, all purchasers of Edwards' common stock during the Class Period suffered similar injury through their purchase of Edwards' common stock at artificially inflated prices, and a presumption of reliance applies.

48. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor

might have considered the omitted information important in deciding whether to buy or sell the subject security.

F. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

49. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with revenue projections while at the same time failing to maintain adequate forecasting processes. Defendants provided the public with forecasts that failed to account for this decline in sales and/or adequately disclose the fact that the Company at the current time did not have adequate forecasting processes.

50. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

51. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Edwards who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

52. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Edwards' common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

53. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Edwards' common stock were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Edwards or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of April 25, 2024, there were 602.6 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

54. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

55. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

56. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Edwards;

(c) whether the Individual Defendants caused Edwards to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Edwards' common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

57. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

58. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

59. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

60. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Edwards common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Edwards' securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

61. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Edwards' securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

62. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of

the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

63. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Edwards' internal affairs.

64. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Edwards' businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Edwards' common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Edwards' common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

65. During the Class Period, Edwards' common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on

the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Edwards' common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Edwards' common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Edwards' common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

66. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

67. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

68. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

69. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their

senior positions, they knew the adverse non-public information about Edwards' misstatements.

70. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Edwards which had become materially false or misleading.

71. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Edwards disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Edwards to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Edwards' common stock.

72. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Edwards to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

73. By reason of the above conduct, the Individual Defendants and/or Edwards are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: October 14, 2024

Respectfully submitted,

LEVI & KORSINSKY LLP

/s/ Adam Apton

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